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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,169	04/19/2001	Theresa Ann Jeary	P24,622 USA	3922

7590 11/15/2002

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EXAMINER
TRAN, SUSAN T

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 11/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/744,169	JEARY ET AL.	
	Examiner	Art Unit	
	Susan Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 20-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 20-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment C, Request for Extension of Time, and Request for Appointment of Associate Attorney filed 09/03/02.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 21, 22, 25-27, and 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Landry et al. US 6,080,736, and Stark et al. US 6,066,339.

Landry teaches methods and compositions for treating and preventing anxiety and anxiety disorders comprising slow or controlled release pharmaceutical formulation suitable for oral administration, such as multi-layer coatings, microparticles, microspheres, osmotic system, or polymer matrices (column 17, lines 15 through column 18, lines 1-58). The composition comprises antidepressant, such as fluvoxamine as active agent; stabilizer; and excipient (column 19, lines 1-28; and claim 15).

Although Landry is silent as to the teaching of the rate-controlled coating, Landry teaches slow/controlled release formulation in the form of multi-layer coating, microspheres or microparticle.

Stark teaches oral multiparticulate formulation comprising drug core being coated with rate-controlling polymer, such as ammonia methacrylate copolymers (column 2, lines 58-65). The formulation further comprising an immediate release coating applied onto the rate-controlling polymer coat, and/or at least two populations of sustained release particles having different in vitro dissolution profiles (column 3, lines 13-53). Thus, it would have been prima facie obvious for one of ordinary skill in the art to modify Landry's multi-layer coating formulation using the rate-controlling coating in view of the teaching of Stark because the references teach the advantageous result of slow/controlled release formulation. The expected result would be a slow/controlled release formulation containing SSRI compound, which is suitable to provide effective plasma levels of drug over at least 24 hours.

Claims 1-5, 20-22, 25-27, 31, 32, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zentner et al. US 4,851,228, in view of Stark et al. US 6,066,339.

Zentner teaches multiparticulate controlled delivery system comprising active core coated with rate controlling water insoluble wall (column 2, lines 57 through column 3, lines 1-10; column 10, lines 59 through column 11, lines 1-51). The active agent can be one or mixture of drugs, such as morphine, codeine, amiflamine, trazedone, doxepin, or fluvoxamine (column 12, lines 49 through column 14, lines 1-14).

Zentner is silent as to the teaching of the specific rate-controlled coating as claimed in claims 5 and 32.

Stark teaches oral multiparticulate formulation comprising drug core being coated with rate-controlling polymer, such as ammonia methacrylate copolymers (column 2, lines 58-65). Thus, it would have been prima facie obvious for one of ordinary skill in the art to modify Zentner's multiparticulate formulation using ammonia methacrylate copolymers as the rate-controlling coating in view of the teaching of Stark. The reason for this modification is to obtain a multiparticulate formulation fro the controlled release of a drug to an environment of use. The expected result would be a slow/controlled release formulation containing antidepressants drug having prolonged release rate.

Claims 23, 24, and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zentner et al. US 4,851,228, in view of Stark et al. US 6,066,339.

Zentner and Stark are relied upon for the reasons stated above. Although the references do not teach the claimed release profile, Stark teaches similar release profile (table in column 15, lines 40-50). Hence, it would have been obvious for one of ordinary skill in the art to, by routine experimentation determine a suitable release rate useful to deliver SSRI compound.

Response to Arguments

Applicant's arguments filed 09/03/02 have been fully considered but they are not persuasive.

Claims 1-5, 21, 22, 25-27, and 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Landry et al. US 6,080,736, and Stark et al. US 6,066,339.

Applicant argues that Landry teaches controlled release of R-tofisopam in conjunction with other compounds, including fluvoxamine. Accordingly, Landry does not teach fluvoxamine may be in the form of particles, or include a rate-controlling polymer coating. Contrary to the applicant's argument, Landry teaches pharmaceutical compositions in the form of microparticles, liposomes and/or microspheres to provide slow or controlled release of the *active ingredient therein* (column 17, lines 59-65). Landry recites in claims 1, 2, 12, and 15 that the dosage form further comprising an antidepressant, such as fluvoxamine. Accordingly, such language does suggest that fluvoxamine can be an active ingredient therein, which can be included in the pharmaceutical compositions in the form of microparticles, liposomes and/or microspheres to provide slow or controlled release.

Stark fails to cure the deficiencies of the Landry reference, since Stark does not teach the use of fluvoxamine. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Landry teaches controlled release dosage form such as polymer matrices, osmotic systems, permeable membranes, but Landry is silent as to the teaching of rate-controlled coating. Stark also teaches controlled release dosage form such as osmotic

systems, permeable membranes, which include rate-controlled coating. Thus, Stark is relied upon solely for the teaching of the rate-controlled coating.

Applicant argues that none of the cited references provide motivation to substitute an SSRI in particle form in the slow/controlled release formulation. Contrary to the applicant's argument, Landry teaches pharmaceutical compositions in the form of microparticles, liposomes and/or microspheres to provide slow or controlled release of the *active ingredient therein* (column 17, lines 59-65). Landry recites in claims 1, 2, 12, and 15 that the dosage form further comprising an antidepressant, such as fluvoxamine. Accordingly, such language does suggest that fluvoxamine can be an active ingredient therein, which can be included in the pharmaceutical compositions in the form of microparticles, liposomes and/or microspheres to provide slow or controlled release. Furthermore, applicant's transitional language "comprises" does not exclude the use of other active ingredient, including R-tofisopam.

Claims 1-5, 20-22, 25-27, 31, 32, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zentner et al. US 4,851,228, in view of Stark et al. US 6,066,339.

Applicant argues that Zentner teaches fluvoxamine in a lengthy list of drugs. However, "[W]hen, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is 'anticipated' ***if one of them is in the prior art.***" Titanium Metals Corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (citing *In re Petering*, 301 F.2d 676, 682, 133 USPQ 275, 280 (CCPA 1962)).

Applicant argues that neither the Zentner nor the Stark provides motivation to substitute the ammonio methacrylate copolymers of the Stark reference in the Zentner formlation t oobtain a multiparticulate formulation. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). Furthermore, applicant's transitional language "comprises" does not exclude the use of other polymer, including ammonio methacrylate compolymers.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0193.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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